

APPLICATION FOR UNITED STATES PATENT

in the name of

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Of

Align Technology, Inc.

For

**METHODS AND SYSTEMS FOR LUBRICATING
DENTAL APPLIANCES**

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5. **METHODS AND SYSTEMS FOR
LUBRICATING DENTAL APPLIANCES**

The present application is a continuation-in-part of Application No. 09/466,353; filed on December 17, 1999, the full disclosure of which is incorporated herein by reference.

10 **BACKGROUND OF THE INVENTION**

1. Field of the Invention

The present invention is related generally to the field of orthodontics. More particularly, the present invention is related to a method and system for incrementally moving teeth from an initial tooth arrangement to a final tooth arrangement.

Repositioning teeth for aesthetic or other reasons is accomplished conventionally by wearing what are commonly referred to as "braces." Braces comprise a variety of appliances such as brackets, archwires, ligatures, and O-rings. Attaching the appliances to a patient's teeth is a tedious and time consuming enterprise requiring many meetings with the treating orthodontist. Consequently, conventional orthodontic treatment limits an orthodontist's patient capacity and makes orthodontic treatment quite expensive.

Before fastening braces to a patient's teeth, at least one appointment is typically scheduled with the orthodontist, dentist, and/or X-ray laboratory so that X-rays and photographs of the patient's teeth and jaw structure can be taken. Also during this preliminary meeting, or possibly at a later meeting, an alginate mold of the patient's teeth is typically made. This mold provides a model of the patient's teeth that the orthodontist uses in conjunction with the X-rays and photographs to formulate a treatment strategy. The orthodontist then typically schedules one or more appointments during which braces will be attached to the patient's teeth.

At the meeting during which braces are first attached, the teeth surfaces are initially treated with a weak acid. The acid optimizes the adhesion properties of the teeth surfaces for brackets and bands that are to be bonded to them. The brackets and bands serve as anchors for other appliances to be added later. After the acid step, the brackets and bands are cemented to the patient's teeth using a suitable bonding material. No force-inducing appliances are added until the cement is set. For this reason, it is common for the orthodontist to schedule a later appointment to ensure that the brackets and bands are well

bonded to the teeth.

The primary force-inducing appliance in a conventional set of braces is the archwire. The archwire is resilient and is attached to the brackets by way of slots in the brackets. The archwire links the brackets together and exerts forces on them to move the teeth over time.

5 Twisted wires or elastomeric O-rings are commonly used to reinforce attachment of the archwire to the brackets. Attachment of the archwire to the brackets is known in the art of orthodontia as "ligation" and wires used in this procedure are called "ligatures." The elastomeric O-rings are called "plastics."

10 After the archwire is in place, periodic meetings with the orthodontist are required, during which the patient's braces will be adjusted by installing a different archwire having different force-inducing properties or by replacing or tightening existing ligatures. Typically, these meetings are scheduled every three to six weeks.

15 As the above illustrates, the use of conventional braces is a tedious and time consuming process and requires many visits to the orthodontist's office. Moreover, from the patient's perspective, the use of braces is unsightly, uncomfortable, presents a risk of infection, and makes brushing, flossing, and other dental hygiene procedures difficult.

20 For these reasons, it would be desirable to provide alternative methods and systems for repositioning teeth. Such methods and systems should be economical, and in particular should reduce the amount of time required by the orthodontist in planning and overseeing each individual patient. The methods and systems should also be more acceptable to the patient, in particular being less visible, less uncomfortable, less prone to infection, and more compatible with daily dental hygiene. At least some of these objectives will be met by the methods and systems of the present invention described hereinafter.

25 2. Description of the Background Art

Tooth positioners for finishing orthodontic treatment are described by Kesling in the *Am. J. Orthod. Oral. Surg.* 31:297-304 (1945) and 32:285-293 (1946). The use of silicone positioners for the comprehensive orthodontic realignment of a patient's teeth is described in Warunek et al. (1989) *J. Clin. Orthod.* 23:694-700. Clear plastic retainers for finishing and
30 maintaining tooth positions are commercially available from Raintree Essix, Inc., New Orleans, Louisiana 70125, and Tru-Tain Plastics, Rochester, Minnesota 55902. The manufacture of orthodontic positioners is described in U.S. Patent Nos. 5,186,623; 5,059,118; 5,055,039; 5,035,613; 4,856,991; 4,798,534; and 4,755,139.

Other publications describing the fabrication and use of dental positioners include Kleemann and Janssen (1996) *J. Clin. Orthodon.* 30:673-680; Cureton (1996) *J. Clin. Orthodon.* 30:390-395; Chiappone (1980) *J. Clin. Orthodon.* 14:121-133; Shilliday (1971) *Am. J. Orthodontics* 59:596-599; Wells (1970) *Am. J. Orthodontics* 58:351-366; and
5 Cottingham (1969) *Am. J. Orthodontics* 55:23-31.

Kuroda et al. (1996) *Am. J. Orthodontics* 110:365-369 describes a method for laser scanning a plaster dental cast to produce a digital image of the cast. See also U.S. Patent No. 5,605,459.

U.S. Patent Nos. 5,533,895; 5,474,448; 5,454,717; 5,447,432; 5,431,562; 5,395,238;
10 5,368,478; and 5,139,419, assigned to Ormco Corporation, describe methods for manipulating digital images of teeth for designing orthodontic appliances.

U.S. Patent No. 5,011,405 describes a method for digitally imaging a tooth and determining optimum bracket positioning for orthodontic treatment. Laser scanning of a molded tooth to produce a three-dimensional model is described in U.S. Patent No.
15 5,338,198. U.S. Patent NO. 5,452,219 describes a method for laser scanning a tooth model and milling a tooth mold. Digital computer manipulation of tooth contours is described in U.S. Patent Nos. 5,607,305 and 5,587,912. Computerized digital imaging of the jaw is described in U.S. Patent Nos. 5,342,202 and 5,340,309. Other patents of interest include U.S. Patent Nos. 5,549,476; 5,382,164; 5,273,429; 4,936,862; 3,860,803; 3,660,900;
20 5,645,421; 5,055,039; 4,798,534; 4,856,991; 5,035,613; 5,059,118; 5,186,623; and 4,755,139.

SUMMARY OF THE INVENTION

The present invention provides improved methods and systems for repositioning
25 teeth from an initial tooth arrangement to a final tooth arrangement. Repositioning is accomplished with a system comprising a series of appliances configured to receive the teeth in a cavity and incrementally reposition individual teeth in a series of at least three successive steps, usually including at least four successive steps, often including at least ten steps, sometimes including at least twenty-five steps, and occasionally including forty or
30 more steps. Most often, the methods and systems will reposition teeth in from ten to twenty-five successive steps, although complex cases involving many of the patient's teeth may take forty or more steps. The successive use of a number of such appliances permits each appliance to be configured to move individual teeth in small increments, typically less than 2

mm, preferably less than 1 mm and more preferably less than 0.5 mm. These limits refer to the maximum linear translation of any point on a tooth as a result of using a single appliance.

The movements provided by successive appliances, of course, will usually not be the same for any particular tooth. Thus, one point on a tooth may be moved by a particular distance as a result of the use of one appliance and thereafter moved by a different distance and/or in a different direction by a later appliance.

The individual appliances will preferably comprise a polymeric shell having the teeth-receiving cavity formed therein, typically by molding as described below. Each individual appliance will be configured so that its tooth-receiving cavity has a geometry corresponding to an intermediate or end tooth arrangement intended for that appliance. That is, when an appliance is first worn by the patient, certain of the teeth will be misaligned relative to an undeformed geometry of the appliance cavity. The appliance, however, is sufficiently resilient to accommodate or conform to the misaligned teeth, and will apply sufficient resilient force against such misaligned teeth in order to reposition the teeth to the intermediate or end arrangement desired for that treatment step.

Systems according to the present invention will include at least a first appliance having a geometry selected to reposition a patient's teeth from the initial tooth arrangement to a first intermediate arrangement where individual teeth will be incrementally repositioned. The system will further comprise at least one intermediate appliance having a geometry selective to progressively reposition teeth from the first intermediate arrangement to one or more successive intermediate arrangements. The system will still further comprise a final appliance having a geometry selected to progressively reposition teeth from the last intermediate arrangement to the desired final tooth arrangement. In some cases, it will be desirable to form the final appliance or several appliances to "over correct" the final tooth position, as discussed in more detail below.

As will be described in more detail below in connection with the methods of the present invention, the systems may be planned and all individual appliances fabricated at the outset of treatment, and the appliances may thus be provided to the patient as a single package or system. The order in which the appliances are to be used will be clearly marked, (e.g. by sequential numbering) so that the patient can place the appliances over his or her teeth at a frequency prescribed by the orthodontist or other treating professional. Unlike braces, the patient need not visit the treating professional every time an adjustment in the treatment is made. While the patients will usually want to visit their treating professionals

periodically to assure that treatment is going according to the original plan, eliminating the need to visit the treating professional each time an adjustment is to be made allows the treatment to be carried out in many more, but smaller, successive steps while still reducing the time spent by the treating professional with the individual patient. Moreover, the ability to use polymeric shell appliances that are more comfortable, less visible, and removable by the patient, greatly improves patient compliance, comfort, and satisfaction.

According to a method of the present invention, a patient's teeth are repositioned from an initial tooth arrangement to a final tooth arrangement by placing a series of incremental position adjustment appliances in the patient's mouth. Each appliance is coated with a lubricious composition on the surface of the dental appliance. Conveniently, the appliances are not affixed and the patient may place and replace the appliances at any time during the procedure. The first appliance of the series will have a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement. After the first intermediate arrangement is approached or achieved, one or more additional (intermediate) appliances will be successively placed on the teeth, where such additional appliances have geometries selected to progressively reposition teeth from the first intermediate arrangement through successive intermediate arrangement(s). The treatment will be finished by placing a final appliance in the patient's mouth, where the final appliance has a geometry selected to progressively reposition teeth from the last intermediate arrangement to the final tooth arrangement. The final appliance or several appliances in the series may have a geometry or geometries selected to over correct the tooth arrangement, i.e. have a geometry which would (if fully achieved) move individual teeth beyond the tooth arrangement which has been selected as the "final." Such over correction may be desirable in order to offset potential relapse after the repositioning method has been terminated, i.e. to permit some movement of individual teeth back toward their pre-corrected positions. Over correction may also be beneficial to speed the rate of correction, i.e. by having an appliance with a geometry that is positioned beyond a desired intermediate or final position, the individual teeth will be shifted toward the position at a greater rate. In such cases, treatment can be terminated before the teeth reach the positions defined by the final appliance or appliances. The method will usually comprise placing at least two additional appliances, often comprising placing at least ten additional appliances, sometimes placing at least twenty-five additional appliances, and occasionally placing at least forty or more additional appliances. Successive appliances will be replaced when the teeth either approach (within a

preselected tolerance) or have reached the target end arrangement for a stage of treatment, typically being replaced at an interval in the range from 2 days to 20 days, usually at an interval in the range from 5 days to 10 days.

Often, it may be desirable to replace the appliances at a time before the "end" tooth arrangement of that treatment stage is actually achieved. It will be appreciated that as the teeth are gradually repositioned and approach the geometry defined by a particular appliance, the repositioning force on the individual teeth will diminish greatly. Thus, it may be possible to reduce the overall treatment time by replacing an earlier appliance with the successive appliance at a time when the teeth have been only partially repositioned by the earlier appliance. Thus, the FDDS can actually represent an over correction of the final tooth position. This both speeds the treatment and can offset patient relapse.

In general, the transition to the next appliance can be based on a number of factors. Most simply, the appliances can be replaced on a predetermined schedule or at a fixed time interval (i.e. number of days for each appliance) determined at the outset based on an expected or typical patient response. Alternatively, actual patient response can be taken into account, e.g. a patient can advance to the next appliance when that patient no longer perceives pressure on their teeth from a current appliance, i.e. the appliance they have been wearing fits easily over the patient's teeth and the patient experiences little or no pressure or discomfort on his or her teeth. In some cases, for patients whose teeth are responding very quickly, it may be possible for a treating professional to decide to skip one or more intermediate appliances, i.e. reduce the total number of appliances being used below the number determined at the outset. In this way, the overall treatment time for a particular patient can be reduced.

In another aspect, methods of the present invention comprise repositioning teeth using appliances comprising polymeric shells having cavities shaped to receive and resiliently reposition teeth to produce a final tooth arrangement. The shells are coated a lubricious composition. The present invention provides improvements to such methods which comprise determining at the outset of treatment geometries for at least three of the appliances which are to be worn successively by a patient to reposition teeth from an initial tooth arrangement to the final tooth arrangement. Preferably, at least four geometries will be determined in the outset, often at least ten geometries, frequently at least twenty-five geometries, and sometimes forty or more geometries. Usually, the tooth positions defined by the cavities in each successive geometry differ from those defined by the prior geometry by

no more than 2 mm, preferably no more than 1 mm, and often no more than 0.5 mm, as defined above.

In still another aspect, methods according to the present invention provide for fabricating a plurality of lubriciously coated dental incremental position adjustment appliances. Said methods comprise providing an initial digital data set, a final digital data set, and producing a plurality of successive digital data sets representing the target successive tooth arrangements, generally as just described. The dental appliances are then fabricated based on at least some of the digital data sets representing the successive tooth arrangements. Preferably, the fabricating step comprises controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the desired tooth arrangements. The dental appliances are then produced as negatives of the positive models using conventional positive pressure or vacuum fabrication techniques. The fabrication machine may comprise a stereolithography or other similar machine which relies on selectively hardening a volume of non-hardened polymeric resin by scanning a laser to selectively harden the resin in a shape based on the digital data set. Other fabrication machines which could be utilized in the methods of the present invention include tooling machines and wax deposition machines.

In still another aspect, methods of the present invention for fabricating a dental appliance comprise providing a digital data set representing a modified tooth arrangement for a patient. A fabrication machine is then used to produce a positive model of the modified tooth arrangement based on the digital data set. The dental appliance is then produced as a negative of the positive model and a lubricious composition is applied to the surface of the dental appliance. The fabrication machine may be a stereolithography or other machine as described above, and the positive model is produced by conventional pressure or vacuum molding techniques.

In a still further aspect, methods for fabricating a dental appliance according to the present invention comprise providing a first digital data set representing a modified tooth arrangement for a patient. A second digital data set is then produced from the first digital data set, where the second data set represents a negative model of the modified tooth arrangement. The fabrication machine is then controlled based on the second digital data set to produce the dental appliance. The fabrication machine will usually rely on selectively hardening a non-hardened resin to produce the appliance. The appliance typically comprises a polymeric shell having a cavity shape to receive and resiliently reposition teeth from an

initial tooth arrangement to modified tooth arrangement. The method includes applying a lubricious composition to the surface of the dental appliance

In another aspect, a method fabricates a dental appliance by providing a first digital data set representing a modified tooth arrangement for a patient; producing a second digital data set from the first data set, wherein the second data set represents a negative model of the modified tooth arrangement; controlling a fabrication machine based on the second digital data set to produce the dental appliance; and applying a lubricious composition to the surface of the dental appliance. The method includes selectively hardening a non-hardened resin to produce the appliance and separating the appliance from the remaining liquid resin. The appliance can be a polymeric shell having a cavity shaped to receive and resiliently reposition teeth from an initial tooth arrangement to the modified tooth arrangement and the appliance is coated with a polar chemical to provide a hydrophilic surface. The chemical is one of hydrogels, 2-HEMA (2-hydroxy ethyl methacrylate), NVP (n-vinyl pyrrolidone), or acrylamide, PEO, PPO, MAA, or AA.

The appliance can be coated with a non-polar chemical to provide a hydrophobic surface, sometimes with an oily substance to provide a hydrophobic surface where oily substance is either PTFE (Poly-tetrafluoroethylene) or silicone or mineral oil. The appliance can be coated with a chemical to make its surface slippery wherein the appliance has a surface adapted to imbibe and hold a micromolecular layer of water to lubricate the lips or the side of the mouth. The composition is applied by a spraying operation, or by using an electro-static discharge and baking, or by a dipping operation.

The surface of the appliance can be pretreated and the precoating treatment can include one or more of the following: corona discharging, acid etching or solvent etching performed by one or more of the following: sanding, abrasion, tumbling and sand blasting.

The surface of appliance can be modified using one or more of the following: coating, grafting, laminating and interpenetrating networks.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A illustrates a patient's jaw and provides a general indication of how teeth may be moved by the methods and apparatus of the present invention.

Fig. 1B illustrates a single tooth from Fig. 1A and defines how tooth movement distances are determined.

Fig. 1C illustrates the jaw of Fig. 1A together with an incremental position

adjustment appliance which has been configured according to the methods of the present invention.

Fig. 2 is a block diagram illustrating the steps of the present invention for producing a system of incremental position adjustment appliances.

5 Fig. 3 is a block diagram setting forth the steps for manipulating an initial digital data set representing an initial tooth arrangement to produce a final digital data set corresponding to a desired final tooth arrangement.

Fig. 4 is a flow chart illustrating an eraser tool for the methods herein.

Fig. 4A illustrates the volume of space which is being erased by the program of Fig.

10 4.

Fig. 5 is a flow chart illustrating a program for matching high-resolution and low-resolution components in the manipulation of data sets of Fig. 3.

Fig. 6 illustrates the method for generating multiple intermediate digital data sets which are used for producing the adjustment appliances of the present invention.

15 Fig. 7 illustrates alternative processes for producing a plurality of appliances according to the methods of the present invention utilizing digital data sets representing the intermediate and final appliance designs.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

20 According to the present invention, systems and methods are provided for incrementally moving teeth using a plurality of discrete appliances, where each appliance successively moves one or more of the patient's teeth by relatively small amounts. The tooth movements will be those normally associated with orthodontic treatment, including translation in all three orthogonal directions relative to a vertical centerline, rotation of the
25 tooth centerline in the two orthodontic directions ("root angulation" and "torque"), as well as rotation about the centerline.

Referring now to Fig. 1A, a representative jaw 100 includes sixteen teeth 102. The present invention is intended to move at least some of these teeth from an initial tooth arrangement to a final tooth arrangement. To understand how the teeth may be moved, an arbitrary centerline (CL) is drawn through one of the teeth 102. With reference to this
30 centerline (CL), the teeth may be moved in the orthogonal directions represented by axes 104, 106, and 108 (where 104 is the centerline). The centerline may be rotated about the axis 108 (root angulation) and 104 (torque) as indicated by arrows 110 and 112, respectively.

Additionally, the tooth may be rotated about the centerline, as represented by arrow 114.

Thus, all possible free-form motions of the tooth can be performed. Referring now to Fig.

1B, the magnitude of any tooth movement achieved by the methods and devices of the present invention will be defined in terms of the maximum linear translation of any point P

5 on a tooth 102. Each point P_i will undergo a cumulative translation as that tooth is moved in any of the orthogonal or rotational directions defined in Fig. 1A. That is, while the point will usually follow a non-linear path, there will be a linear distance between any point in the tooth when determined at any two times during the treatment. Thus, an arbitrary point P_i may in fact undergo a true side-to-side translation as indicated by arrow d_1 , while a second
10 arbitrary point P_2 may travel along an arcuate path, resulting in a final translation d_2 . Many aspects of the present invention are defined in terms of the maximum permissible movement of a point P_i induced by the methods in any particular tooth. Such maximum tooth movement, in turn, is defined as the maximum linear translation of that point P_i on the tooth which undergoes the maximum movement for that tooth in any treatment step.

15 Referring now to Fig. 1C, systems according to the present invention will comprise a plurality of incremental position adjustment appliances. The appliances are intended to effect incremental repositioning of individual teeth in the jaw as described generally above. In a broadest sense, the methods of the present invention can employ any of the known positioners, retainers, or other removable appliances which are known for finishing and
20 maintaining teeth positions in connection with conventional orthodontic treatment. The systems of the present invention, in contrast with prior apparatus and systems, will provide a plurality of such appliances intended to be worn by a patient successively in order to achieve the gradual tooth repositioning as described herein. A preferred appliance 100 will comprise a polymeric shell having a cavity shaped to receive and resiliently reposition teeth from one
25 tooth arrangement to a successive tooth arrangement. The polymeric shell will preferably, but not necessarily, fit over all teeth present in the upper or lower jaw. Often, only certain one(s) of the teeth will be repositioned while others of the teeth will provide a base or anchor region for holding the repositioning appliance in place as it applies the resilient repositioning force against the tooth or teeth to be repositioned. In complex cases, however, many or most
30 of the teeth will be repositioned at some point during the treatment. In such cases, the teeth which are moved can also serve as a base or anchor region for holding the repositioning appliance. Additionally, the gums and/or the palette can serve as an anchor region, thus allowing all or nearly all of the teeth to be repositioned simultaneously.

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The polymeric appliance 100 of Fig. 1C is preferably formed from a thin sheet of a suitable elastomeric polymeric, such as Tru-Tain 0.03 in. thermal forming dental material, Tru-Tain Plastics, Rochester, Minnesota 55902. Usually, no wires or other means will be provided for holding the appliance in place over the teeth. In some cases, however, it will be desirable or necessary to provide individual anchors on teeth with corresponding receptacles or apertures in the appliance 100 so that the appliance can apply an upward force on the tooth which would not be possible in the absence of such an anchor. Specific methods for producing the appliances 100 are described hereinafter.

Referring now to Fig. 2, the overall method of the present invention for producing the incremental position adjustment appliances for subsequent use by a patient to reposition the patient's teeth will be described. As a first step, a digital data set representing an initial tooth arrangement is obtained, referred to hereinafter as the IDDS. The IDDS may be obtained in a variety of ways. For example, the patient's teeth may be scanned or imaged using well known technology, such as X-rays, three-dimensional X-rays, computer-aided tomographic images or data sets, magnetic resonance images, etc. Methods for digitizing such conventional images to produce data sets useful in the present invention are well known and described in the patent and medical literature. Usually, however, the present invention will rely on first obtaining a plaster cast of the patient's teeth by well known techniques, such as those described in Graber, *Orthodontics: Principle and Practice*, Second Edition, Saunders, Philadelphia, 1969, pp. 401-415. After the tooth casting is obtained, it can be digitally scanned using a conventional laser scanner or other range acquisition system to produce the IDDS. The data set produced by the range acquisition system may, of course, be converted to other formats to be compatible with the software which is used for manipulating images within the data set, as described in more detail below. General techniques for producing plaster casts of teeth and generating digital models using laser scanning techniques are described, for example, in U.S. Patent No. 5,605,459, the full disclosure of which is incorporated herein by reference.

There are a variety of range acquisition systems, generally categorized by whether the process of acquisition requires contact with the three dimensional object. A contact-type range acquisition system utilizes a probe, having multiple degrees of translational and/or rotational freedom. By recording the physical displacement of the probe as it is drawn across the sample surface, a computer-readable representation of the sample object is made. A non-contact-type range acquisition device can be either a reflective-type or transmissive-

type system. There are a variety of reflective systems in use. Some of these reflective systems utilize non-optical incident energy sources such as microwave radar or sonar. Others utilize optical energy. Those non-contact-type systems working by reflected optical energy further contain special instrumentation configured to permit certain measuring techniques to be performed (e.g., imaging radar, triangulation and interferometry).

A preferred range acquisition system is an optical, reflective, non-contact-type scanner. Non-contact-type scanners are preferred because they are inherently nondestructive (i.e., do not damage the sample object), are generally characterized by a higher capture resolution and scan a sample in a relatively short period of time. One such scanner is the Cyberware Model 15 manufactured by Cyberware, Inc., Monterey, California.

Either non-contact-type or contact-type scanners may also include a color camera, that when synchronized with the scanning capabilities, provides a means for capturing, in digital format, a color representation of the sample object. The importance of this further ability to capture not just the shape of the sample object but also its color is discussed below.

The methods of the present invention will rely on manipulating the IDDS at a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images. Specific aspects of the software will be described in detail hereinafter. While the methods will rely on computer manipulation of digital data, the systems of the present invention comprising multiple dental appliances having incrementally differing geometries may be produced by non-computer-aided techniques. For example, plaster casts obtained as described above may be cut using knives, saws, or other cutting tools in order to permit repositioning of individual teeth within the casting. The disconnected teeth may then be held in place by soft wax or other malleable material, and a plurality of intermediate tooth arrangements can then be prepared using such a modified plaster casting of the patient's teeth. The different arrangements can be used to prepare sets of multiple appliances, generally as described below, using pressure and vacuum molding techniques. While such manual creation of the appliance systems of the present invention will generally be much less preferred, systems so produced will come within the scope of the present invention.

Referring again to Fig. 2, after the IDDS has been obtained, the digital information will be introduced to the computer or other workstation for manipulation. In the preferred approach, individual teeth and other components will be "cut" to permit their individual repositioning or removal from the digital data. After thus "freeing" the components, the user

will often follow a prescription or other written specification provided by the treating professional. Alternatively, the user may reposition them based on the visual appearance or using rules and algorithms programmed into the computer. Once the user is satisfied with the final arrangement, the final tooth arrangement is incorporated into a final digital data set (FDDS).

Based on both the IDDS and the FDDS, a plurality of intermediate digital data sets (INTDDS's) are generated to correspond to successive intermediate tooth arrangements. The system of incremental position adjustment appliances can then be fabricated based on the INTDDS's, as described in more detail below.

Fig. 3 illustrates a representative technique for manipulating the IDDS to produce the FDDS on the computer. Usually, the data from the digital scanner will be in a high resolution form. In order to reduce the computer time necessary to generate images, a parallel set of digital data set representing the IDDS at a lower resolution will be created. The user will manipulate the lower resolution images while the computer will update the high resolution data set as necessary. The user can also view/manipulate the high resolution model if the extra detail provided in that model is useful. The IDDS will also be converted into a quad edge data structure if not already present in that form. A quad edge data structure is a standard topological data structure defined in *Primitives for the Manipulation of General Subdivisions and the Computation of Voronoi Diagrams*, ACM Transactions of Graphics, Vol. 4, No. 2, April 1985, pp. 74-123. Other topological data structures, such as the winged-edge data structure, could also be used.

As an initial step, while viewing the three-dimensional image of the patient's jaw, including the teeth, gingivae, and other oral tissue, the user will usually delete structure which is unnecessary for image manipulation and/or final production of an appliance. These unwanted sections of the model may be removed using an eraser tool to perform a solid modeling subtraction. The tool is represented by a graphic box. The volume to be erased (the dimensions, position, and orientation of the box) are set by the user employing the GUI.

Typically, unwanted sections would include extraneous gum area and the base of the originally scanned cast. Another application for this tool is to stimulate the extraction of teeth and the "shaving down" of tooth surfaces. This is necessary when additional space is needed in the jaw for the final positioning of a tooth to be moved. The treating professional may choose to determine which teeth will be shaved and/or which teeth will be extracted. Shaving allows the patient to maintain their teeth when only a small amount of space is

needed. Typically, extraction and shaving, of course, will be utilized in the treatment planning only when the actual patient teeth are to be extracted and/or shaved prior to initiating repositioning according to the methods of the present invention.

Removing unwanted and/or unnecessary sections of the model increases data processing speed and enhances the visual display. Unnecessary sections include those not needed for creation of the tooth repositioning appliance. The removal of these unwanted sections reduces the complexity and size of the digital data set, thus accelerating manipulations of the data set and other operations.

After the user positions and sizes the eraser tool and instructs the software to erase the unwanted section, all triangles within the box set by the user will be removed and the border triangles are modified to leave a smooth, linear border. The software deletes all of the triangles within the box and clips all triangles which cross the border of the box. This requires generating new vertices on the border of the box. The holes created in the model at the faces of the box are re-triangulated and closed using the newly created vertices.

The saw tool is used to define the individual teeth (or possibly groups of teeth) to be moved. The tool separates the scanned image into individual graphic components enabling the software to move the tooth or other component images independent of remaining portions of the model. The saw tool defines a path for cutting the graphic image by using two cubic B-spline curves lying in space, possibly constrained to parallel planes. A set of lines connects the two curves and shows the user the general cutting path. The user may edit the control points on the cubic B-splines, the thickness of the saw cut, and the number of erasers used, as described below.

Thickness: When a cut is used to separate a tooth, the user will usually want the cut to be as thin as possible. However, the user may want to make a thicker cut, for example, when shaving down surrounding teeth, as described above. Graphically, the cut appears as the curve bounded by half the thickness of the cut on each side of the curve.

Number of Erasers: A cut is comprised of multiple eraser boxes arranged next to each other as a piecewise linear approximation of the Saw Tool's curve path. The user chooses the number of erasers, which determines the sophistication of the curve created - the greater the number of segments, the more accurately the cutting will follow the curve. The number of erasers is shown graphically by the number of parallel lines connecting the two cubic B-spline curves. Once a saw cut has been completely specified the user applies the cut to the model. The cut is performed as a sequence of erasings. A preferred algorithm is set forth in

Fig. 4. Fig. 4A shows a simultaneous raising iteration of the cut as described by the algorithm.

A preview feature may also be provided in the software. The preview feature visually displays a saw cut as the two surfaces that represent opposed sides of the cut. This allows the user to consider the final cut before applying it to the model data set.

After the user has completed all desired cutting operations with the saw tool, multiple graphic solids exist. However, at this point, the software has not determined which triangles of the quad edge data structure belong to which components. The software chooses a random starting point in the data structure and traverses the data structure using adjacency information to find all of the triangles that are attached to each other, identifying an individual component. This process is repeated starting with the triangle whose component is not yet determined. Once the entire data structure is traversed, all components have been identified.

To the user, all changes made to the high resolution model appear to occur simultaneously in the low resolution model, and vice versa. However, there is not a one-to-one correlation between the different resolution models. Therefore, the computer "matches" the high resolution and low resolution components as best as it can subject to defined limits. The algorithm is described in Fig. 5.

After the teeth and other components have been placed or removed so that the final tooth arrangement has been produced, it is necessary to generate a treatment plan, as illustrated in Fig. 6. The treatment plan will ultimately produce the series of INTDDS's and FDDS as described previously. To produce these data sets, it is necessary to define or map the movement of selected individual teeth from the initial position to the final position over a series of successive steps. In addition, it may be necessary to add other features to the data sets in order to produce desired features in the treatment appliances. For example, it may be desirable to add wax patches to the image in order to define cavities or recesses for particular purposes. For example, it may be desirable to maintain a space between the appliance and particular regions of the teeth or jaw in order to reduce soreness of the gums, avoid periodontal problems, allow for a cap, and the like. Additionally, it will often be necessary to provide a receptacle or aperture intended to accommodate an anchor which is to be placed on a tooth in order to permit the tooth to be manipulated in a manner that requires the anchor, e.g. lifted relative to the jaw.

Some methods for manufacturing the tooth repositioning appliances require that the separate, repositioned teeth and other components be unified into a single continuous

structure in order to permit manufacturing. In these instances, "wax patches" are used to attach otherwise disconnected components of the INTDDS's. These patches are added to the data set underneath the teeth and above the gum so that they do not effect the geometry of the tooth repositioning appliances. The application software provides for a variety of wax patches to be added to the model, including boxes and spheres with adjustable dimensions. The wax patches that are added are treated by the software as additional pieces of geometry, identical to all other geometries. Thus, the wax patches can be repositioned during the treatment path as well as the teeth and other components.

In the manufacturing process, which relies on generation of positive models to produce the repositioning appliance, adding a wax patch to the graphic model will generate a positive mold that has the same added wax patch geometry. Because the mold is a positive of the teeth and the appliance is a negative of the teeth, when the appliance is formed over the mold, the appliance will also form around the wax patch that has been added to the mold.

When placed in the patient's mouth, the appliance will thus allow for a space between the inner cavity surface of the appliance and the patient's teeth or gums. Additionally, the wax patch may be used to form a recess or aperture within the appliance which engages an anchor placed on the teeth in order to move the tooth in directions which could not otherwise be accomplished.

In addition to such wax patches, an individual component, usually a tooth, can be scaled to a smaller or larger size which will result in a manufactured appliance having a tighter or looser fit, respectively.

Treatment planning is extremely flexible in defining the movement of teeth and other components. The user may change the number of treatment stages, as well as individually control the path and speed of components.

Number of Treatment Stages: The user can change the number of desired treatment stages from the initial to the target states of the teeth. Any component that is not moved is assumed to remain stationary, and thus its final position is assumed to be the same as the initial position (likewise for all intermediate positions, unless one or more key frames are defined for that component).

Key frames: The user may also specify "key frames" by selecting an intermediate state and making changes to component position(s). Unless instructed otherwise, the software automatically linearly interpolates between all user-specified positions (including the initial position, all key frame positions, and the target position). For example, if only a

final position is defined for particular component, each subsequent stage after the initial stage will simply show the component an equal linear distance and rotation (specified by a quaternion) closer to the final position. If the user specifies two key frames for that component, it will "move" linearly from the initial position through different stages to the position defined by the first key frame. It will then move, possibly in a different direction, linearly to the position defined by the second key frame. Finally, it will move, possibly in yet a different direction, linearly to the target position.

The user can also specify non-linear interpolation between the key frames. A spline curve is used to specify the interpolating function in a conventional manner.

These operations may be done independently to each component, so that a key frame for one component will not affect another component, unless the other component is also moved by the user in that key frame. One component may accelerate along a curve between stages 3 and 8, while another moves linearly from stage 1 to 5, and then changes direction suddenly and slows down along a linear path to stage 10. This flexibility allows a great deal of freedom in planning a patient's treatment.

Lastly, the software may incorporate and the user may at any point use a "movie" feature to automatically animate the movement from initial to target states. This is helpful for visualizing overall component movement throughout the treatment process.

Above it was described that the preferred user interface for component identification is a three dimensional interactive GUI. A three-dimensional GUI is also preferred for component manipulation. Such an interface provides the treating professional or user with instant and visual interaction with the digital model components. It is preferred over interfaces that permit only simple low-level commands for directing the computer to manipulate a particular segment. In other words, a GUI adapted for manipulation is preferred over an interface that accepts directives, for example, only of the sort: "translate this component by 0.1 mm to the right." Such low-level commands are useful for fine-tuning, but, if they were the sole interface, the processes of component manipulation would become a tiresome and time-consuming interaction.

Before or during the manipulation process, one or more tooth components may be augmented with template models of tooth roots. Manipulation of a tooth model augmented with a root template is useful, for example, in situations where impacting of teeth below the gumline is a concern. These template models could, for example, comprise a digitized representation of the patient's teeth x-rays.

The software also allows for adding annotations to the database which can comprise text and/or the sequence number of the apparatus. The annotation is added as recessed text (i.e. it is 3-D geometry), so that it will appear on the printed positive model. If the annotation can be placed on a part of the mouth that will be covered by a repositioning appliance, but is unimportant for the tooth motion, the annotation may appear on the delivered repositioning appliance(s).

The above-described component identification and component manipulation software is designed to operate at a sophistication commensurate with the operator's training level. For example, the component manipulation software can assist a computer operator, lacking orthodontic training, by providing feedback regarding permissible and forbidden manipulations of the teeth. On the other hand, an orthodontist, having greater skill in intraoral physiology and teeth-moving dynamics, can simply use the component identification and manipulation software as a tool and disable or otherwise ignore the advice.

Once the intermediate and final data sets have been created, the appliances may be fabricated as illustrated in Fig. 7. Preferably, fabrication methods will employ a rapid prototyping device 200 such as a stereolithography machine. A particularly suitable rapid prototyping machine is Model SLA-250/50 available from 3D System, Valencia, California.

The rapid prototyping machine 200 will selectively harden a liquid or other non-hardened resin into a three-dimensional structure which can be separated from the remaining non-hardened resin, washed, and used either directly as the appliance or indirectly as a mold for producing the appliance. The prototyping machine 200 will receive the individual digital data sets and produce one structure corresponding to each of the desired appliances.

Generally, because the rapid prototyping machine 200 may utilize a resin having non-optimum mechanical properties and which may not be generally acceptable for patient use, it will be preferred to use the prototyping machine to produce molds which are, in effect, positive tooth models of each successive stage of the treatment. After the positive models are prepared, a conventional pressure or vacuum molding machine may be used to produce the appliances from a more suitable material, such as 0.03 inch thermal forming dental material, available from Tru-Tain Plastics, Rochester, Minnesota 55902. Suitable pressure molding equipment is available under the tradename BIOSTAR from Great Lakes Orthodontics, Ltd., Tonawanda, New York 14150. The molding machine 250 produces each of the appliances directly from the positive tooth model and the desired material. Suitable vacuum molding machines are available from Raintree Essix, Inc.

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The appliances next sent to a station that coats the surface of the appliances with a lubricious composition, which can be a hydrophilic composition or a hydrophobic composition. The lubricated appliances increase lubricity on the surface of the appliances so that, when worn, the appliance surface appears to be smooth to the labial surface of the mouth and to the tongue. In one embodiment, the hydrophilic composition can be a composition called Hydrocoat™ coating that is used on catheters to make them more lubricious. In another embodiment, the hydrophobic composition can be a composition called Microglide™. The nature of the coating may be hydrophilic or hydrophobic. Alternatively, the material may be selected so that the surface of the material has a low surface energy that renders the surface slippery.

In the manner discussed above, the appliance is coated with a chemical to make its surface slippery. The appliance can be coated with polar chemical to provide a hydrophilic surface. Alternatively, the appliance can be coated with non-polar chemical to provide a hydrophobic surface.

The coating can be a hydrophilic chemical where the surface imbibes and holds a micromolecular layer of water to lubricate the lips or the side of the mouth. Potential hydrophilic materials include hydrogels, 2-HEMA (2-hydroxy ethyl methacrylate), methoxy ethoxy ethyl methacrylate, NVP (n-vinyl pyrrolidone), and acrylamide, PEO (polyethylene oxide) at various molecular weights, PPO (polypropylene oxide) at various molecular weights, acrylic and methacrylic acids. In other embodiments where an oily coating is used to provide slippery feeling, materials such as PTFE, mineral oil, and silicone oil can be used.

The coated appliances remove two sources of discomfort arising from wearing the appliances. First, the coated appliance reduces a sensation relating to the thickness of the appliance. Second, the coated appliance reduces the feeling of dryness on the teeth because the surface of the appliance is hydrophilic.

The coatings can be sprayed onto the appliances. Alternatively, the appliances can be dipped into a tray containing the coating materials. Other methods of applying the coatings can be used as well. For example, the coating can be applied using a suitable electro-static spray, followed by baking. Additionally, under certain circumstances, the coating does not adhere to the surface of the aligner well, and in such cases, the surface can be pretreated to aid in the adhesion. A number of pre-coating treatment methods may be used such as corona discharge, acid, and/or solvent etching. Also, mechanical methods may be used also such as sanding, abrasion, tumbling and sand blasting. The surface of the appliances can be

modified through coating, g...ng, laminating, or interpenetrating w... networks, where a chemical is incorporated into a matrix of the material for the appliance. The desired chemical comes to the surface when the appliance is properly positioned in the mouth.

After production, the plurality of appliances which comprise the system of the present invention are preferably supplied to the treating professional all at one time. The appliances will be marked in some manner, typically by sequential numbering directly on the appliances or on tags, pouches, or other items which are affixed to or which enclose each appliance, to indicate their order of use. Optionally, written instructions may accompany the system which set forth that the patient is to wear the individual appliances in the order marked on the appliances or elsewhere in the packaging. Use of the appliances in such a manner will reposition the patient's teeth progressively toward the final tooth arrangement.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.